HFI-35 6/10/98

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Los Angeles District
19900 MacArthur Boulevard Suite 300
Irvine, California 92612-2445

Telephone (714) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 4, 1998

WL-33-8

WARNING LETTER

Mr. Mark E. Farraj
Owner
Tropical Sun Tanning Resort
1034 W. Arrow Highway, Suite F
San Dimas, CA 91773

Dear Mr. Farraj:

During a field test of tanning beds located at Tropical Sun Tanning Resort, 1034 W. Arrow Highway, Suite F, San Dimas, CA 91773, on May 14, 1998, the following item of noncompliance with the Federal Performance Standard for Sunlamp Products, 21 CFR 1040.20 was disclosed.

As required by 21 CFR 1040.20(c)(3) control for termination of radiation emission was not present in three rooms. Three of your SunDash Intellian Plus, Platinum R26P beds, were modified and their termination of radiation switches were non-operational. These three beds, bearing serial numbers 1743, 358 and 359 were located in rooms five, seven and nine.

You must respond in writing within 15 days of receipt of this letter and indicate the number of the referenced products which have been modified and your choice of one of the following options:

A. Refutation - You may submit your views and evidence to establish that the alleged non-compliance does not exist.

B. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30, 1003.31).

C. Corrective Action - If you neither refute the non-compliance nor request an exemption, then you must submit a written corrective action plan (CAP) to fulfill your obligations under 21 CFR 1004.1 to repair, or replace the violative products.

Corrective Action Plan - Instructions for preparation of a corrective action plan may be found in 21 CFR 1004.2, 1004.3 or 1004.4.

If you request additional time to prepare your refutation, notification, corrective action plan, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response.

Due to the serious health hazards involved in the deficiencies noted above, it is requested that the products not be used until appropriate corrections have been made.

When you have completed all changes necessary to assure compliance of the units, and have submitted to the Center for Devices and Radiological Health and the District Office identified below describing these changes and any other information required to assure that the products comply with the performance standard, you may then resume the operation of the above mentioned beds.

Please advise this office within 15 days of receipt of this letter of any actions you have taken or intend to take. If you do not respond within 15 days, then the Agency will consider you to be in violation of Section 360B(a)(4) of the Radiation Control for Health and Safety Act.

If further information is required, please contact Dannie E. Rowland at (949)798-7649 or write to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612-2445

Sincerely,

Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234-7320